

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: June 27, 2012

Submitter: Shanghai Jinta Medical Co., Ltd.
No. 18, Jianding Road, Fengjing Town, Jinshan District, Shanghai,
China

Primary Contact Person: Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Consulting Co., Ltd
Tel: +86-20-62321333
Fax: +86-20-86330253

Secondary Contact Person: Mr. Wang Changqing
Vice General Manager
Shanghai Jinta Medical Co., Ltd.
+86-21-67361700

NOV 26 2013

Device: Trade Name: Disposable infusion set

Common/Usual Name: Disposable infusion set

Classification Names: Class II per Code of Federal Regulations,
Title 21, 880.5440, Intravascular Administration Sets

Product Code: FPA

Predicate Device(s): K083687

Device Description: The applicant device-JT series disposable infusion set is plastic, single-use, sterile disposable infusion device, which is intended to be used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

The protective cap is intended to protect the needle; The puncturing needle is made of Polyethylene and used to pierce the container; the catheter is made of Polyvinyl chloride and used to connect various components; the drip is transparent so that the user can observe the dropping condition of the medical solution, and it has a filtration mesh which can prevent the micro particle with diameter larger than 200 um to from entering human vessel; Flow regulator is used to adjust the flow rate from zero to maximum; Male conical fitting is used for connecting with vein needle for medical solution transfusion.

The proposed device is provided sterilized.

Intended Use: JT series Disposable infusion set is used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

Technology: Shanghai Jinta JT series Disposable infusion set is Constructed of high grade extruded Polyvinyl Chloride (PVC). The primary components of Jinta Disposable infusion set are manufactured to identical or similar specifications of the predicated devices listed above. The intended use, basic design, function and materials used are identical or similar to the predicated devices. The technical characteristic is substantially equivalent to the predicate devices. For details refer to the SE section in the application package.

Determination of Substantial Equivalence: **Summary of Non-Clinical Tests:**

The Disposable infusion set and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, Disposable infusion set, did not require clinical studies to support substantial equivalence.

Conclusion: Shanghai Jinta Medical Co., Ltd considers the JT series Disposable infusion set to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

Shanghai Jinta Medical Company, Limited
C/O Mike Gu
Guangzhou Osmunda Medical Device Consulting Co., Ltd.
Guangzhou, Guangdong
CHINA 510420

Re: K131646

Trade/Device Name: Disposable Infusion Set, Models JT-DST1 and JT-DST2
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: August 20, 2013
Received: August 30, 2013

Dear Mr. Gu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kwame O.
Ulmer S

for

Erin Keith M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K131646

Device Name
Disposable Infusion Set, Models JT-DST1 and JT-DST2

Indications for Use (Describe)

JT series Disposable infusion set is used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



Digitally signed by Richard C.
Chapman

Date: 2013.11.26 12:25:02 -05'00'